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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/440,384	11/15/1999	HOWARD A. KINGSFORD	05918-153001	2883

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FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER

PATTERSON, MARC A

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/440,384

Applicant(s)

KINGSFORD, HOWARD A.

Examiner

Marc A Patterson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

REPEATED REJECTIONS

1. The 35 U.S.C. 102(b) rejection of Claims 4, 10, 16 – 17, 19 – 21 and 23 as being anticipated by Reed et al. (U.S. Patent No. 5,312,456), of record on page 2 of the previous Action, is repeated.

The 35 U.S.C. 103(a) rejection of Claims 2 – 3, 5 – 9, 11 – 12 and 18 as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456), of record on page 4 of the previous Action, is repeated.

The 35 U.S.C. 103(a) rejection of Claim 13 as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456) in view of Fye (U.S. Patent No. 5,031,609), of record on page 6 of the previous Action, is repeated.

The 35 U.S.C. 103(a) rejection of Claims 14 – 15 as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456) in view of Coates (U.S. Patent No. 4,219,019), of record on page 7 of the previous Action, is repeated.

ANSWERS TO APPLICANT'S ARGUMENTS

2. Applicant's arguments regarding the 35 U.S.C. 102(b) rejection of Claims 2 – 12 and 16 – 23 as being anticipated by Reed et al. (U.S. Patent No. 5,312,456), 35 U.S.C. 103(a) rejection of Claims 2 – 3, 5 – 9, 11 – 12 and 18 as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456), 35 U.S.C. 103(a) rejection of Claim 13 as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456) in view of Fye (U.S. Patent No. 5,031,609), and 35 U.S.C. 103(a) rejection of Claims 14 – 15 as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456) in

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view of Coates (U.S. Patent No. 4,219,019), of record in the previous Action, have been considered but have not been found to be persuasive for the reasons set forth below.

Rejection under 102(b)

Applicant argues, on page 8 of the remarks dated May 26, 2004, that Reed et al do not disclose penetrating elements in which the elements, including each retention barb, is formed integrally of a single plastic resin because Reed et al do not disclose a penetrating elements that are all formed of a single layer of plastic.

However, penetrating elements that are all formed from a single layer of plastic are not claimed. Furthermore, as stated on page 3 of the previous Action, the penetrating elements disclosed by Reed et al comprise a single plastic resin (polysulphone; column 3, lines 44 – 45), and the skin penetrating elements are integral with the backing, and are therefore formed integrally (column 3, lines 32 – 34).

Applicant also argues on page 8 that the shanks of the elements are of one resin in Reed et al, whereas the barbs are of another. However, Reed et al disclose a base, head and support, and therefore a shank and barb, made of a rigid material comprising polysulphone (column 3, lines 40 – 44) and therefore made of a single resin.

Applicant also argues, on page 9, in reference to Applicant's previous declaration, that the method taught by Reed et al necessitates forming the heads of a different material than the substrate in order to obtain lateral undercutting; the penetrating elements, Applicant argues, are therefore not formed from a single plastic resin.

However, as stated above, Reed et al clearly disclose a penetrating element formed from a single plastic resin, polysulphone. Furthermore, Reed et al disclose the method of making only

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with reference to penetrating elements comprising silicone, not with regard to elements comprising plastic; the method is also defined by Reed et al as 'a method' of making, thus making it clear that the invention is not limited to the disclosed method.

Applicant also argues, on page 9, that Reed et al do not enable making or using a skin attachment.

However, a method of making or using is not claimed, and furthermore limitations directed to a method of making or using would be given little patentable weight, as the claimed invention is directed to a product.

Applicant also argues on page 9 that it is stated, and not responded to, in Applicant's prior declaration, that Reed et al do not teach a technique for manufacturing a barb in which the base, head and support are formed integrally from a single plastic resin.

Rejection under 103(a)

However, a technique for manufacturing a barb is not claimed, as stated above.

Applicant also argues on page 10 that the claimed invention is non – obvious over the prior art, even in view of In re Dailey, as Applicant has explained the significance of the recited steps with respect to skin penetration and retention.

However, it is unclear as to which explanation Applicant is referring. Furthermore, no evidence has been provided that a result has been obtained for the claimed conical shape that would not otherwise be expected.

Applicant also argues, on page 11, that it would not be obvious to vary the cited parameters to obtain a desired flexibility.

However, as stated on page 5 of the previous Action, Reed et al teach a desired flexibility and therefore teach the selection of the parameters of the penetration element to obtain the desired flexibility.

Applicant also argues on page 11 that Claims 13 – 15 are patentable over the prior art for the reasons discussed with regard to Claim 19. In response, the arguments above are repeated.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc Patterson, whose telephone number is (571) 272 – 1497.

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The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by phone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached at (571) 272 - 1498. FAX communications should be sent to (703) 872-9310. FAXs received after 4 P.M. will not be processed until the following business day.

Marc A. Patterson, PhD.

Marc Patterson
Art Unit 1772

Harold Pyon
HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

9/28/04